AIMED ALLIANCE

April 8, 2019

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Re: Docket OIG-0936-P – Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Secretary Azar:

Aimed Alliance is a 501(c)(3) non-profit organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for providing us with the opportunity to comment on Docket OIG-0936-P, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*.

This proposed rule would amend the Federal Anti-Kickback Statute (AKS) by removing the safe harbor for rebates that drug makers provide to contracted Medicare Part D plan sponsors, Medicaid Managed Care Organizations (MCOs), and Pharmacy Benefit Managers (PBMs).[1] Additionally, the proposed rule would create new safe harbor protections for point-of-sale price reductions for prescription medications and flat PBM service fees.[2] We support this proposed rule because it has the potential to lower drug prices and increase access to medically necessary treatments.

I. Aimed Alliance Supports the Rebate Rule

Price reductions and remuneration provided by drug makers, known as "rebates," have been a feature of the pharmaceutical supply chain for many years. However, health care stakeholders have often pointed to pharmaceutical rebates as primary drivers of cost growth among pharmaceutical products.[3] By reconfiguring how rebates flow through the pharmaceutical supply chain, HHS could bring price relief to many consumers who require costly medications.

Aimed Alliance supports the proposed rule because it may incentivize drug makers to lower their drug prices and disincentivize middlemen to give more costly medications preferential formulary placement based primarily on the value and volume of rebates collected.

[1] https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals
[2] https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals
[3] https://www.nytimes.com/2018/07/27/health/rebates-high-drug-prices-trump.html

The proposed rule may also help to ensure that consumers are benefitting from discounts that are negotiated on their behalf. To achieve this goal, the U.S Department of Health and Human Services (HHS) Office of Inspector General (OIG) must ensure that these discounts are passed through to consumers. CMS recently issued guidance related to this proposed rule that outlined how the agency would begin implementing the safe harbor modifications as a two-year voluntary demonstration project.[4] We believe that this is a step in the right direction to ensure that the proposal works as intended.

A. Removing the Safe Harbor for Rebates May Lower Costs for Consumers

Removing the safe harbor for rebates that drug makers pay to middlemen may result in lower drug prices, and therefore, lower out-of-pocket costs for many consumers. Drug makers are incentivized to increase list prices to make their medications more attractive to middlemen because rebates are based on a percentage of a medication's list price. The higher the list price, the greater the value is to middlemen. For products with strong competition, this incentive is even greater because manufacturers may need to offer middlemen greater remuneration to secure placement on their formulary.

Removing the safe harbor would reduce the risk of middlemen offering preferred formulary positions to costlier medications that have traditionally had higher rebate values. Without this incentive, drug makers may find it necessary to lower their prices across the board, and PBMs may respond by offering access to a broader selection of medications on their health plan's formulary.

B. Adding a Safe Harbor for Point-of-Sale Rebates May Lower Costs for Consumers and Improve Access to Medically Necessary Treatment

Creating a safe harbor in the AKS for point-of-sale rebates may result in lower out-of-pocket costs for consumers taking the medications for which the rebates are offered. With lower out-of-pocket costs, such consumers may be able to afford medically necessary treatments that may have otherwise been too expensive. Higher list prices result in increased out-of-pocket costs for consumers. Many patients, including those participating in Medicare Part D, are responsible for coinsurance, which is calculated based on the medication's list price, before rebates.[5] Therefore, for these patients, out-of-pocket costs are directly tied to list prices. Additionally, those who are in high deductible health plans must also pay the list price until they meet their deductible requirements. If a medication has a high list price, the patient may be responsible for the entire deductible upfront. While many patients could use drug makers' copayment assistance programs to help defray some of these expenses, patients who are participating in federal health programs are excluded from utilizing such assistance.[6]

Greater cost-sharing responsibilities have been shown to have a negative impact on the

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[4] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf
[5] https://www.healthaffairs.org/do/10.1377/hblog20190215.708286/full/
[6] https://www.healthaffairs.org/do/10.1377/hpb20171409.000176/full/

ability of patients to remain adherent to their treatment plan.[7] Some patients ration their medications by taking less than the prescribed amount to make the prescription last longer.[8] Others skip refills. Others may choose to not fill their medications at all. Research from IQVIA demonstrates that when cost-sharing exceeds $250 to fill a prescription, 69 percent of patients in private plans abandon their medication altogether, which carries even greater risks.[9] This type of behavior is dangerous, and can lead to disease progression, relapse, and other negative health outcomes.[10] In contrast, lower out-of-pocket costs will benefit patients by improving their ability to maintain adherence to their treatment plan.[11]

Rebate arrangements are also problematic because they distort how money moves among participants of health insurance risk pools. Health insurance has classically existed to protect against catastrophic health costs by spreading them across the risk pool when they are incurred.[12] Health plans often use rebates to reduce premium costs for all plan enrollees.[13] When a plan enrollee fills a prescription for a more costly medication, rebate dollars likely flow to that enrollee's health plan rather than to that individual enrollee. The enrollee only benefits from the rebate in the form of slightly reduced premiums. As such, the sick enrollees are subsidizing the healthy enrollees, rather than the inverse. It would be more equitable for the enrollee filling the prescription to directly benefit from any rebate that is associated with that medication.

C. Adding a Safe Harbor for Flat Service Fees May Ensure that Middlemen Receive Appropriate Compensation

By moving to a flat fee arrangement rather than percentage-based remuneration, the proposed rule may allow middlemen to receive appropriate payment for the value of their services rather than the value or volume of the medication. As such, the safe harbor may correct the broken rebate system.

The current practice of offering rebates in the pharmaceutical supply chain arose as a result of *In re Brand Name Prescription Drugs Antitrust Litigation*, a class action lawsuit.[14] In this litigation, plaintiff pharmacies alleged that drug makers were engaging in anticompetitive price discrimination in violation of the Robinson-Patman Act through selective up-front discounts.[15] The plaintiff pharmacies alleged that drug makers were giving favorable discounts to managed care payers but were not providing similar discounts to pharmacies.[16] In a settlement,

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[7] https://catalyst.phrma.org/69-percent-of-patients-abandon-medicines-when-cost-sharing-is-more-than-250
[8] https://www.cnn.com/2019/01/30/health/rising-drug-costs/index.html
[9] https://catalyst.phrma.org/69-percent-of-patients-abandon-medicines-when-cost-sharing-is-more-than-250
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6045499/
[11] https://healthitanalytics.com/news/cost-is-a-primary-driver-of-medication-non-adherence-rates
[12] https://healthpayerintelligence.com/news/how-to-create-balanced-risk-pools-that-lower-premiums
[13] https://news.bloomberglaw.com/health-law-and-business/insight-eliminating-drug-rebates-could-raise-insurance-premiums
[14] https://www.pcmanet.org/wp-content/uploads/2018/07/Legal-Analysis_-Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf
[15] https://www.pcmanet.org/wp-content/uploads/2018/07/Legal-Analysis_-Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf
[16] https://www.pcmanet.org/wp-content/uploads/2018/07/Legal-Analysis_-Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf

the defendant drug makers agreed to offer equal discounts to both pharmacies and managed care payers.[17]

Drug makers responded to this settlement by offering rebates instead of up-front discounts.[18] Up-front discounts are a front-end mechanism used to reward middlemen based on the anticipated volume of pharmaceutical products that such middlemen could move.[19] Conversely, rebates are a back-end mechanism for which value is determined after middlemen have completed their transactions and demonstrated the volume of the products moved.[20] Transitioning from up-front discounts to rebates allows drug makers to offer the same pricing mechanism to all middlemen, which spares this activity from antitrust scrutiny.[21] However, while rebates are offered to all middlemen on the same terms, middlemen are not all able to compete equally because they do not have the same capacity to move the same volume of the manufacturer's product. This culminates in manufacturers having the capacity to play favorites among middlemen without the behavior being considered anticompetitive.

In contrast, moving to a flat service fee achieves the intended goal of the settlement. Drug makers would pay for the value of the middlemen's services rather than the paying based on the value or volume of the medication. The same pricing mechanisms could be used across the board, and the risk of playing favorites would be reduced.

II. HHS Must Study the Impact of the Proposed Rule and Adjust Accordingly

If the modifications to the AKS safe harbors do not work as anticipated, it could cause health costs to rise for all consumers. Consumers currently rely on some benefit flowing to them in the form of reduced premiums afforded by rebate dollars flowing into the health plan. However, if HHS-OIG eliminates the safe harbor protections for these rebates, it is possible that drug makers could keep their prices high, and also opt not to pass rebates on to consumers at the point-of-sale. Moreover, without rebates, PBMs could make up for lost revenue by increasing premiums and copays. If that is the case, all plan participants may experience increased out-of-pocket costs. This outcome should be avoided. Therefore, as CMS implements this proposed rule as a voluntary demonstration project for the next two years,[22] we urge HHS-OIG to study the outcomes of the demonstration project and adjust the parameters of the rule accordingly.

Thank you for providing us with the opportunity to comment on this proposed rule. We hope that you find value in our recommendations and we hope that you will continue

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[17] https://www.pcmanet.org/wp-content/uploads/2018/07/Legal-Analysis_-Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf
[18] https://www.pcmanet.org/wp-content/uploads/2018/07/Legal-Analysis_-Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf
[19] https://foleyhoag.com/publications/ebooks-and-white-papers/2018/august/antitrust-implications-of-hhs-proposal-to-limit-manufacturer-rebates
[20] https://foleyhoag.com/publications/ebooks-and-white-papers/2018/august/antitrust-implications-of-hhs-proposal-to-limit-manufacturer-rebates
[21] https://foleyhoag.com/publications/ebooks-and-white-papers/2018/august/antitrust-implications-of-hhs-proposal-to-limit-manufacturer-rebates
[22] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf

thoughtfully engaging with this issue to ensure that the proposed changes create the intended results.

Sincerely,

John Wylam
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